

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**  
Painters District Council No. 30 Health and Welfare Fund

**(b)** County of Residence of First Listed Plaintiff Kane County, IL  
(EXCEPT IN U.S. PLAINTIFF CASES)

**(c)** Attorneys (Firm Name, Address, and Telephone Number)  
Deborah R. Gross  
Law Offices Bernard M. Gross, P.C.  
100 Penn Square East, Suite 450  
Philadelphia, PA 19107  
215-561-3600; debbie@bernardmgross.com

**DEFENDANTS**  
WARNER CHILCOTT PUBLIC LIMITED COMPANY, WARNER CHILCOTT COMPANY, INC., WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT HOLDINGS COMPANY III, LTD, WARNER CHILCOTT CORPORATION, WARNER CHILCOTT SALES, INC.

County of Residence of First Listed Defendant  
(IN U.S. PLAINTIFF CASES ONLY)  
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)  
☐ 1 U.S. Government Plaintiff  
☒ 3 Federal Question (U.S. Government Not a Party)  
☐ 2 U.S. Government Defendant  
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)  
(For Diversity Cases Only)  

Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)  

<b>CONTRACT</b> <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>TORTS</b> <b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<b>FORFEITURE/PENALTY</b> <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<b>BANKRUPTCY</b> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<b>OTHER STATUTES</b> <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input checked="" type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
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**REAL PROPERTY**  
☐ 210 Land Condemnation  
☐ 220 Foreclosure  
☐ 230 Rent Lease & Ejectment  
☐ 240 Torts to Land  
☐ 245 Tort Product Liability  
☐ 290 All Other Real Property

**CIVIL RIGHTS**  
☐ 440 Other Civil Rights  
☐ 441 Voting  
☐ 442 Employment  
☐ 443 Housing/Accommodations  
☐ 445 Amer. w/Disabilities Employment  
☐ 446 Amer. w/Disabilities Other  
☐ 448 Education

**PRISONER PETITIONS**  
**Habeas Corpus:**  
☐ 463 Alien Detainee  
☐ 510 Motions to Vacate Sentence  
☐ 530 General  
☐ 535 Death Penalty  
**Other:**  
☐ 540 Mandamus & Other  
☐ 550 Civil Rights  
☐ 555 Prison Condition  
☐ 560 Civil Detainee - Conditions of Confinement

**V. ORIGIN** (Place an "X" in One Box Only)  
☒ 1 Original Proceeding  
☐ 2 Removed from State Court  
☐ 3 Remanded from Appellate Court  
☐ 4 Reinstated or Reopened  
☐ 5 Transferred from Another District (specify)  
☐ 6 Multidistrict Litigation

**VI. CAUSE OF ACTION**  
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
Brief description of cause:

**VII. REQUESTED IN COMPLAINT:**  
☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.  
DEMAND \$ undetermined  
CHECK YES only if demanded in complaint:  
JURY DEMAND: ☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY** (See instructions):  
JUDGE Cynthia M. Rufe DOCKET NUMBER 2:13-cv-3476  
DATE 07/12/2013  
SIGNATURE OF ATTORNEY OF RECORD  
FOR OFFICE USE ONLY  
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE



FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: c/o Law Offices Bernard M. Gross, P.C., 100 Penn Square East, Suite 450, Philadelphia, PA 19107

Address of Defendant: c/o Ballard, Spahr, Andrews and Ingersoll, 1735 Market Street, 51st Floor, Philadelphia, PA 19103

Place of Accident, Incident or Transaction: Pennsylvania

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))

Yes ☐

No ☒

Does this case involve multidistrict litigation possibilities?

Yes ☐

No ☒

RELATED CASE, IF ANY:

Case Number: 2:13-cv-3476; 13-1807; 13-2000;  
13-2014, 13-2892

Judge Cynthia M. Rufe

Date Terminated: \_\_\_\_\_

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?

Yes ☐

No ☒

2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?

Yes ☒

No ☐

3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?

Yes ☐

No ☒

4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?

Yes ☐

No ☒

CIVIL: (Place ☒ in ONE CATEGORY ONLY)

A. Federal Question Cases:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☒ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases  
(Please specify) \_\_\_\_\_

B. Diversity Jurisdiction Cases:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify) \_\_\_\_\_
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases  
(Please specify) \_\_\_\_\_

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Deborah R. Gross

, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$50,000.00 exclusive of interest and costs;

☐ Belief other than monetary damages is sought

DATE: July 12, 2013

Attorney-at-Law

44542

Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: July 12, 2013

Attorney-at-Law

44542

Attorney I.D.#

JUL 12 2013



**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**CASE MANAGEMENT TRACK DESIGNATION FORM**

PAINTERS DISTRICT COUNCIL NO. 30  
HEALTH & WELFARE FUND

CIVIL ACTION

V.

**13 4065**

WARNER CHILCOTT PUBLIC LIMITED COMPANY, WARNER CHILCOTT COMPANY, INC., WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT HOLDINGS COMPANY III, LTD, WARNER CHILCOTT CORPORATION, WARNER CHILCOTT SALES (US) LLC, ACTAVIS, INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., LUPIN LTD., and LUPIN INC.

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ☒ ( )
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

July 12, 2013

Deborah R. Gross

Plaintiff

Date

Attorney-at-law

Attorney for

215-561-3600

215-561-3000

debbie@bernardmgross.com

Telephone

FAX Number

E-Mail Address

JUL 12 2013



**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF  
PENNSYLVANIA**

PAINTERS DISTRICT COUNCIL NO. 30  
HEALTH & WELFARE FUND,  
Individually And On Behalf Of All Others  
Similarly Situated,

Plaintiff,

v.

Civil Action No. **13 4065**

**COMPLAINT - CLASS ACTION**

**JURY TRIAL DEMANDED**

WARNER CHILCOTT PUBLIC LIMITED  
COMPANY, WARNER CHILCOTT  
COMPANY, INC., WARNER CHILCOTT  
COMPANY, LLC, WARNER CHILCOTT (US),  
LLC, WARNER CHILCOTT LABORATORIES  
IRELAND LIMITED, WARNER CHILCOTT  
HOLDINGS COMPANY III, LTD, WARNER  
CHILCOTT CORPORATION, WARNER  
CHILCOTT SALES (US) LLC, ACTAVIS,  
INC., WATSON PHARMACEUTICALS, INC.,  
WATSON LABORATORIES, INC., LUPIN  
LTD., and LUPIN INC.,

Defendants.

Plaintiff Painters District Council No. 30 Health and Welfare Fund, ("Plaintiff" or "Painters Fund"), on behalf of itself and all others similarly situated, files this Class Action Complaint ("Complaint") against Defendants Warner Chilcott Public Limited Company, Warner Chilcott Company, Inc., Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, Warner Chilcott Laboratories Ireland, Limited, Warner Chilcott Holdings Company III, Ltd, Warner Chilcott Corporation, Warner Chilcott Sales (US), LLC (collectively, "Warner Chilcott"), Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively, "Watson"), Lupin Ltd., and Lupin Inc. (collectively "Lupin") (Watson and Lupin

are collectively referred to as "Generic Defendants," and Warner Chilcott and the Generic Defendants are collectively referred to as the "Defendants"), based upon personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, and alleges as follows:

## **I. NATURE OF THE ACTION**

1. This is a civil antitrust action seeking treble damages arising out of Defendants' anticompetitive scheme to unlawfully allocate the market for oral contraceptive comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 mcg ethinyl estradiol) and 4 ferrous fumarate tablets (placebo), which Warner Chilcott sells under the brand-name Loestrin 24 Fe ("Loestrin 24"). As alleged below, Defendants' market-allocation scheme injured Plaintiff and the class of end-payor purchasers it seeks to represent (as defined below), causing them to pay overcharges.

2. Warner Chilcott has sold Loestrin-based oral contraceptive products in the United States since 1973. Although the basic method of using norethindrone acetate, ethinyl estradiol, and a placebo to prevent pregnancy has been known for decades, Warner Chilcott has continued to seek and obtain new patents on minor variations of those basic ingredients, using its massive sales force to serially encourage doctors to write prescriptions for the latest version of Loestrin. Warner Chilcott's various formulation patents are weak and subject to challenge by generic manufacturers as invalid, unenforceable, and not infringed.

3. As alleged in detail below, when faced with the prospect of imminent generic competition to its formulation known as Loestrin 24 Fe, Warner Chilcott paid the generic manufacturers, Defendants Watson and Lupin, to withdraw their challenges to the patent and delay entry into the market. Warner Chilcott then used that delay to switch as many Loestrin

24 prescriptions as possible to yet another new formulation of Loestrin — one that would not face generic competition for another several years.

4. As detailed further below, Warner Chilcott sued for patent infringement the generic drug manufacturers that submitted applications to the FDA for approval to sell generic versions of Loestrin 24, asserting that the generics infringe Warner Chilcott's U.S. Patent No. 5,552,394 ("the '394 Patent"). Warner Chilcott filed these patent lawsuits without regard to whether or not they had legal merit. Its purpose in filing the lawsuits was not to win them, but to use them to delay the onset of generic competition. Under the applicable provisions of the Hatch-Waxman Act (discussed in detail below), the mere filing of these lawsuits prevented the FDA from approving the generic drug for 30 months, regardless of the merits of the lawsuit. To get the automatic 30 months of delay, Warner Chilcott did not have to win the patent cases, it only had to file them.

5. Warner Chilcott knew that the '394 Patent was not in fact strong enough to prevent generic competition, i.e., that Warner Chilcott could not get preliminary injunctions based on the patent and in fact was very likely to lose the patent cases if they were litigated to conclusion. Therefore, as the 30-month stay against the first potential generic competitor — Defendant Watson — was nearing expiration, on or about January 9, 2009, Warner Chilcott simply paid Watson to withdraw its challenge to the patent and delay entry into the market. In exchange for substantial payments from Warner Chilcott — for a share of the monopoly profits that the lack of generic competition made possible — Watson agreed to stay out of the market until January 2014 — just six months before the '394 Patent expires.

6. Warner Chilcott repeated this ploy with the second potential generic competitor, Defendant Lupin. As detailed below, the '394 Patent also was not strong enough to prevent

competition from Lupin, and Warner Chilcott was very likely to lose the patent case if it was litigated to conclusion. So Warner Chilcott again agreed to share some of the monopoly profits with its potential competitor. In exchange for substantial payments from Warner Chilcott, Lupin agreed to withdraw its challenge to the patent and delay entry until July 2014 — to the very end of the patent term.

7. Having literally bought itself more time without generic competition, Warner Chilcott used that time to impair generic competition even beyond the expiration of the '394 Patent in July 2014. Warner Chilcott currently is engaged in a "product hop," whereby it is converting prescriptions for Loestrin 24 Fe, which will face generic competition beginning in January 2014, to prescriptions for a follow-on branded product that is ostensibly patent protected until February 2029. Warner-Chilcott's follow-on product is called Lo Loestrin Fe ("Lo Loestrin").

8. Lo Loestrin provides no medical, convenience, or other benefits to patients as compared to Loestrin 24. Instead, best medical practice is not to switch a woman to a new type of oral contraceptive if she is doing well on an existing regimen. Moreover, scientific studies have shown that women have a 50% greater chance of becoming pregnant while taking Lo Loestrin as compared to Loestrin Fe. Nevertheless, beginning in January 2011, Warner Chilcott has instructed its army of sales representatives to urge doctors to stop writing prescriptions for Loestrin 24 and start writing them for Lo Loestrin.

9. Absent the unlawful payments from Warner Chilcott to each of Watson and Lupin to delay the launch of their generic versions of Loestrin 24, Warner Chilcott would never have even begun selling Lo Loestrin, or if it had, it would have made very few sales. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the

market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. Lo Loestrin offers no such benefits. Warner Chilcott's ploy of switching prescriptions to Lo Loestrin depended on launching Lo Loestrin before generic versions of Loestrin 24 were available. Absent Warner Chilcott's unlawful payments to Watson and Lupin, generic Loestrin 24 would have been available long before the Food and Drug Administration ("FDA") approved Lo Loestrin for sale. Consequently, Warner Chilcott would not have launched Lo Loestrin or, if it had, it would have made few sales.

10. But for the anticompetitive scheme and agreements alleged herein, a generic version of Loestrin 24 would have been available to Plaintiff and members of the Class in the United States as early as September 2009, when the FDA granted final approval to Watson's generic Loestrin 24 Fe. Other generic versions of Loestrin 24, including an authorized generic version marketed directly or indirectly by Warner Chilcott, would have subsequently entered, driving the generic prices to down near marginal cost. Plaintiff and the members of the Class would have purchased those generic products. Moreover, absent the anticompetitive scheme and agreements alleged herein, Warner Chilcott would not have been able since January 2011 to substantially reduce the number of Loestrin 24 Fe prescriptions available for generic substitution.

11. Defendants' unlawful scheme and agreements were designed to and did in fact delay the entry of less expensive generic oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets in the United States; fix, raise, maintain or stabilize the price of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets products; allocate



100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets market to Warner Chilcott.

12. Plaintiff brings this action as a class action on behalf of all Indirect Purchasers in the United States of America who purchased or paid for branded and/or generic Loestrin 24 Fe products, other than for re-sale, since September 2009 (*see* Class Definition below). Plaintiff seeks a judgment declaring that Defendants' anticompetitive scheme and agreements, as further described below, are unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiff also seeks an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of the anticompetitive scheme and agreements. Unless enjoined, Defendants' unlawful conduct will continue unchecked and Plaintiff and the End-Payor Class will continue to bear the financial brunt of Defendants' antitrust violations.

13. Plaintiff also asserts claims for compensatory and/or treble damages and equitable relief for continuing violations of state antitrust and/or consumer protection laws, and for unjust enrichment and disgorgement under common law.

## **II. PARTIES**

14. Plaintiff Painters District Council No. 30 Health and Welfare Fund ("Painters Fund") is located in Aurora, Illinois. Painters Fund is an "employee welfare benefit plan" and an "employee benefit plan" within the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§1002(1), 1002(3) and 1003(a). As such, Painters Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Painters Fund is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health coverage for its participants and beneficiaries. Painters Fund is an indirect

purchaser of Loestrin (and will purchase its generic equivalent once it becomes available) during the Class Period and was injured by Defendants' unlawful conduct, as alleged herein. Painters Fund sustained injury when it purchased, paid for and/or provided reimbursement for purchases of Loestrin. Painters Fund paid more for Loestrin than it otherwise would have paid absent the Defendants' wrongful and unlawful conduct. As alleged herein, Painters Fund is entitled to recover damages and under the equitable remedy of unjust enrichment for purchases made by members in various states.

15. Defendant Warner Chilcott Public Limited Company is a company organized and existing under the laws of Ireland, having its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland L2 00000.

16. Defendant Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico. This Defendant holds an approved New Drug Application from the FDA for a formulation of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets, which it sells throughout the United States under the brand name Loestrin 24 Fe. This Defendant is a wholly owned subsidiary of Warner Chilcott PLC.

17. Defendant Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

18. Defendant Warner Chilcott Holdings Company III, Ltd. is a privately-owned, for-profit company organized and existing under and the laws of Bermuda, having its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866.

19. Defendant Warner Chilcott Laboratories Ireland Limited is a company organized and existing under the laws of the Republic of Ireland, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

20. Warner Chilcott Company, Inc., is a company organized and existing under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

21. Warner Chilcott Sales (US), LLC is a Delaware limited liability company with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

22. Warner Chilcott Corporation is a Delaware corporation with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

23. The foregoing defendants are collectively referred to herein as "Warner Chilcott."

24. Actavis, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

25. Watson Pharmaceuticals, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

26. Watson Laboratories, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which is now Actavis, Inc.

27. Actavis, Inc., Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are collectively referred to herein as "Watson." Watson is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

28. Lupin Ltd. is a company organized and existing under the laws of India, having its principal place of business at B/4 Laxami Towers, Branda Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

29. Lupin Pharmaceuticals Inc. is a corporation organized and existing under the laws of Virginia, having its principal place of business at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals Inc. is a wholly-owned subsidiary of Lupin Ltd.

30. Lupin Ltd. and Lupin Pharmaceuticals Inc. are collectively referred to herein as "Lupin." Lupin is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

31. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

### **III. JURISDICTION AND VENUE**

32. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds



\$5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

33. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiff brings claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants' violations of Section 1 of the Sherman Antitrust Act, 15 U.S. C. § 1. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

34. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

#### **IV. INDUSTRY BACKGROUND**

##### **A. Characteristics of the Prescription Pharmaceutical Marketplace**

35. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

36. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists

from dispensing many pharmaceutical products, including Loestrin 24, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

37. Warner Chilcott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

38. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the 'price elasticity of demand' — the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise the price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise the price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

**B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs**

39. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

40. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

41. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

**1. The Hatch-Waxman Amendments**

42. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand

manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

43. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

44. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

45. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled \$21.6 billion; by 2009 total prescription drug revenue had soared to \$300 billion.



## **2. Paragraph IV Certifications**

46. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
- ii. that the patent for the brand drug has expired (a "Paragraph II certification");
- iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
- iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

47. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

48. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic

versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market; generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

49. Brand manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV Litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

50. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic

drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

51. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic manufacturers to conspire in order to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months from filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements. Forfeiture under the MMA most commonly occurs for failure to obtain tentative approval within the requisite 30 months.

52. Under the "failure to market" provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

53. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers subvert the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in a Paragraph IV litigation.

54. In addition, brand and generic manufacturers can structure their settlements in a way that grants 180 days of exclusivity to the generic even where it is likely that the generic has forfeited that exclusivity under one of the applicable MMA forfeiture provisions, e.g., the failure to obtain tentative approval within 30 months of submitting a substantially complete ANDA. This results in a windfall to the generic and a subversion of the regulatory scheme. Because FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that retain de facto exclusivity — even where there should be forfeit de jure under the MMA — dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180 day period; because the



lion's share of the generic revenues will perceivably go to the first filer, subsequent filers have less incentive to litigate to judgment.

**C. The Benefits of Generic Drugs**

55. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that about one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. As a result, competition from generic drugs is viewed by brand name drug companies such as Warner Chilcott as a grave threat to their bottom lines.

56. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

57. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the

industry pricing structure, pharmacies typically earn a higher markup on generics than on brands. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so they offer their members lower copays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

58. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

59. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the Agreements at issue here.

#### **D. The Impact of Authorized Generics**

60. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer's subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an

authorized generic during the 180-day exclusivity period substantially reduces the first-filer's revenue, and substantially reduces drug prices for consumers.

61. In its recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the FTC found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

62. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiff and the End-Payor Class benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

63. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers such as Plaintiff and the End-Payor Class of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

**V. THE ANTICOMPETITIVE SCHEME: SUE GENERICS, THEN PAY THEM TO DELAY ENTRY**

**A. Warner Chilcott Files Paragraph IV Litigation Against Watson**

64. Unlike traditional oral contraceptives that contain 21 active tablets and 7 placebo tablets, Loestrin 24 contains 24 active tablets (containing 1 mg of norethindrone acetate and 20 mcg of ethinyl estradiol) and 4 placebo tablets (containing ferrous fumarate). Warner Chilcott markets Loestrin 24's longer, 24-day active tablet regimen as providing an effective low dose birth control associated with shorter, lighter periods with less bleeding. Other oral contraceptives are not AB-rated to Loestrin 24, cannot be automatically substituted for Loestrin 24 by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Loestrin 24, and thus are not economic substitutes for, nor reasonably interchangeable with, Loestrin 24.

65. On April 15, 2005, Warner Chilcott submitted NDA 21-871 seeking FDA approval to market what became known as Loestrin 24. The FDA approved the NDA on February 17, 2006.

66. In connection with its Loestrin 24 NDA, Warner Chilcott listed the '394 Patent in the FDA Orange Book as covering Loestrin 24 or a method of using Loestrin 24. The purported invention described in the '394 Patent is a method of female contraception which is characterized by a reduced incidence of breakthrough bleeding which comprises administering the claimed combination of estrogen and progestin for 23-25 consecutive days of a 28-day cycle. Warner Chilcott is the fifth owner of the '394 Patent, which issued in September 1996 to the Eastern Virginia Medical School ("EVMS"). EVMS sold the application that became the '394 Patent to Warner Lambert, which was acquired by Pfizer in 2000. Galen Holdings PLC (which acquired Warner Chilcott PLC in 2000), acquired the '394



Patent from Pfizer in March 2003. In July 2004, Galen Holdings, PLC changed its name to Warner Chilcott. Loestrin 24 is the purported commercial embodiment of the '394 Patent.

67. The active ingredients in Loestrin 24, the hormones norethindrone acetate and ethinyl estradiol, are not protected by any patent. In fact, norethindrone and ethinyl estradiol have served as the active ingredients in oral contraceptives dating back to at least the early 1970s. For example, Warner Chilcott's Loestrin Fe 1/20 product—which contains tablets identical to those used in Loestrin 24 Fe—was approved by the FDA on April 30, 1973. The only difference between the '394 Patent (and the corresponding Loestrin 24 product) and Loestrin Fe 1/20—which has been on the market for close to forty years—is that the '394 Patent claims require 23-25 days of tablets whereas the Loestrin 1/20 product was packaged in units of 21 active tablets.

68. Because the '394 Patent claims only a narrow method of using active ingredients that have been used for decades as an oral contraceptive to prevent pregnancy, generic manufacturers were eager to apply for FDA approval to market generic versions of Loestrin 24 before the expiration of the '394 Patent. The generic manufacturers believed that they could obtain a court ruling that the '394 Patent was invalid and unenforceable.

69. On or about June 19, 2006, Generic Defendant Watson notified Warner Chilcott that Watson had filed ANDA No. 78-267, seeking to market a generic version of Loestrin 24. Watson's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Loestrin 24 product would not infringe any valid claim of the '394 Patent.

70. On July 28, 2006, Warner Chilcott filed suit in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Watson's generic Loestrin 24 product would infringe the '394 Patent.

71. Warner Chilcott filed the patent infringement case against Watson without regard to the merits of the case. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Watson from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott was very likely to have lost.

72. During the litigation, Watson conducted discovery supporting a host of defenses focusing on: (1) the enforceability of the '394 Patent; (2) the validity of the '394 Patent; and (3) the strength of Warner Chilcott's infringement allegations.

73. On January 23, 2008, Watson submitted an Amended Answer and Counterclaim asserting that the claims of the '394 Patent are invalid under one or more of 35 U.S.C. §§ 102, 103 and 112. Watson asserted, for example, that the only difference between Loestrin 24 and Warner Chilcott's prior art product Loestrin Fe 1/20-23 to 25 days of active tablets versus 21 14-days of active tablets—was trivial, particularly given that doctors routinely advised women using oral contraceptives to take more than 21 tablets in a row in order to delay the onset of menses that might otherwise occur at an inconvenient time. According to Watson, the claims of the '394 Patent were invalid because simply extending the regimen of a well-known prior art product by several days, as is taught in the literature and was practiced by women, was obvious.

74. Watson also alleged in its Counterclaim that the '394 Patent was unenforceable under equitable doctrines, including inequitable conduct, common law fraud and unclean hands. Watson alleged, *inter alia*, that the applicants for the '394 Patent intentionally: (1) concealed from the PTO an invalidating public use of the claimed invention that occurred more than one year before the application filing date; (2) made false statements and withheld material information; and (3) withheld prior art teaching an extended regimen of oral contraceptives (more than 21 days).

75. For example, one product, Loestrin Fe 1/20, which was known prior to the '394 patent and thus was prior art, was known to be associated with a high incidence of breakthrough bleeding and an unacceptable failure rate, problems that the prior art suggests can be alleviated by extending the number of days per cycle during which active pills are administered. Loestrin Fe 1/20 was only administered for 21 days, but suggested 23-25 days in the claims of the patent. Loestrin Fe 1/20 further suggested that in low-dose oral contraceptives, the 7-day pill free period leads to follicular development, which may lead to pregnancy. Loestrin Fe 1/20 suggested that to provide improved suppression of follicular development by using a 24-day regime of active pills in oral contraceptive products while increasing the progestogen. One of ordinary skill in the art would have been motivated to administer Loestrin Fe 1/20 for additional days to alleviate the known problems associated with its administration over 21 days. Accordingly, the 394 patent could be subjected to invalidity as obvious in view of the prior art.

76. To prevent generic entry using just the '394 Patent (rather than pay-offs), Warner Chilcott would have had to defeat each of Watson's arguments regarding invalidity and unenforceability and prove that Watson infringed the '394 Patent. Warner Chilcott instead

decided to protect its monopoly by paying Watson to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24. And that is precisely what it did, in concert with Watson.

**B. Warner Chilcott and Watson Enter an Exclusion Payment Agreement**

77. Having obtained the goal of the patent case — the 30-month stay — Warner Chilcott decided to end the case. On or about January 9, 2009, just one month before the 30-month stay was to expire, Warner Chilcott and Watson entered into an Exclusion Payment Agreement. Pursuant to that Agreement, Warner Chilcott ended its '394 Patent litigation against Watson, and Watson dropped its Counterclaims against Warner Chilcott. At the time of the unlawful agreement, the court hearing the patent case had not issued any substantive rulings regarding the merits of the case.

78. Under the Exclusion Payment Agreement, Watson agreed to delay launching its generic Loestrin 24 product until the earliest of: (1) January 22, 2014; (2) 180 days before a date on which Warner Chilcott granted rights to a third party to market a generic version of Loestrin 24 in the United States; or (3) the date on which another generic version of Loestrin 24 entered the market.

79. As the *quid pro quo* for Watson's agreement to drop its challenge to the '394 Patent and to delay entry of its generic Loestrin 24 Fe product, Warner Chilcott agreed to pay Watson substantial sums. Warner Chilcott's payments to Watson under the Agreement took at least five forms.

80. First, the Agreement prohibits Warner Chilcott from launching an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing. The Agreement expressly prohibits Warner Chilcott or its affiliates from marketing or supplying, or granting any



third party rights to launch, an authorized generic during the 180-day period. Absent the Agreement, Warner Chilcott had the incentive and ability to launch an authorized generic version of Loestrin 24. Warner Chilcott has marketed authorized generic versions of its other branded drugs, including its oral contraceptive, Dovonex. This aspect of the Agreement provides substantial compensation to Watson, which can expect to make approximately double the unit sales, at a much higher price, absent an authorized generic in the market. These higher prices come at the expense of Plaintiff and the End-Payor Class.

81. Second, Warner Chilcott agreed to grant to Watson a license to market Loestrin 24 *everywhere in the world* beginning January 22, 2014. The license to market Loestrin 24 outside the United States as well as inside the United States has substantially more value to Watson than a license to market the product only in the United States. But that license for foreign marketing has no value to consumers in the United States.

82. Third, the Agreement provides that Warner Chilcott will pay Watson annual fees and a percentage of net sales above a specified level in connection with Watson's co-promotion of Femring, a Warner Chilcott hormone therapy product, beginning in 2009.

83. Fourth, the Agreement gives Watson the exclusive right to earn highly profitable brand sales of a Warner Chilcott oral contraceptive that was in late-stage development at the time of the Agreement. Watson now markets that product under the brand name Generess Fe, a chewable oral contraceptive. Watson has already earned tens of millions of dollars selling Generess Fe in the United States since its launch in May 2011.

84. Fifth, Warner Chilcott agreed not to grant a license to any other manufacturer to enter with a generic version of Loestrin 24 until at least 180 days after Watson entered the market. Warner Chilcott thus guaranteed to Watson a period of 180 days of exclusivity as the

only generic Loestrin 24 on the market, absent another generic manufacturer outlasting a 30-month stay or obtaining a court order permitting such entry. Watson, however, likely forfeited its entitlement to 180-day exclusivity under the Hatch-Waxman Act because it failed to obtain tentative FDA approval to market generic Loestrin 24 within 30 months of first submitting its ANDA in April 2006. Thus, the contractual exclusivity granted by Warner Chilcott had substantial value to Watson, again at the expense of Plaintiff and other End-Payors.

85. If, for some reason, Watson did not forfeit its 180-day exclusivity, then its agreement with Warner Chilcott created a bottleneck preventing FDA from approving any subsequent ANDA until 180 days after January 22, 2014. In a February 19, 2013 earnings call, Paul Bisaro, Watson's Chief Executive Officer, President and Director, represented that Watson retains 180-day exclusivity on Loestrin 24. Bisaro did not say, however, whether that exclusivity is the product of the Agreement or Hatch Waxman. Either way, Defendants win at the expense of consumers because either Watson obtained additional payment in the form of guaranteed six-month exclusivity, or Watson agreed to delay its launch in exchange for (other) payments, thereby creating an approval bottleneck that prevents other generics from entering the market until six months after Watson.

86. Warner Chilcott made these payments in exchange for Watson's agreement to delay generic competition to Loestrin 24 for over four years (or earlier under certain circumstances). Absent Watson's agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not have agreed to: (a) refrain from launching, or granting a license to others to launch, an authorized generic Loestrin 24 during Watson's first 180 days of marketing; (b) designate Watson as a co-promotor of Femring; (c)

grant Watson an exclusive license to market and sell Generess Fe; (d) guarantee Watson 180 days of exclusivity, which it had otherwise forfeited, to market a generic version of Loestrin 24; and/or (e) grant the price and/or other terms that it did under those provisions of the Agreement. Warner Chilcott paid Watson for delayed market entry of generic Loestrin 24.

**C. Warner Chilcott Files Paragraph IV Litigation Against Lupin**

87. As the first-filer, Watson had an opportunity to earn 180 days of exclusivity under the Hatch-Waxman Act. That circumstance created an economic incentive for other generic manufacturers to delay filing their own challenges to the '394 Patent while Watson litigated against Warner Chilcott. If Watson had obtained an order finding the patent invalid or unenforceable, other generic manufacturers would have benefitted from that ruling without having to incur the costs of patent litigation.

88. On or about July 2009, six months after the announcement of the Warner Chilcott/Watson agreement, Lupin notified Warner that it had filed ANDA No. 091398, seeking to market generic versions of Loestrin 24. Lupin's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 Patent.

89. On or about September 9, 2009, Warner sued Lupin for infringement of the '394 Patent in the United States District Court for the District of Delaware (Civil Action No. 0900673). Lupin answered the complaint on October 21, 2009, and alleged special defenses, including invalidity of the '394 Patent and non-infringement.

90. Warner Chilcott filed the case against Lupin without regard to its merits. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Lupin from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic

competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott was very likely to have lost.

91. During discovery, Lupin, like Watson before it, uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the '394 Patent (2) the validity of its claims; and (3) the strength of Warner Chilcott's infringement allegations.

92. To prevent generic entry using just the '394 Patent (rather than pay-offs), Warner Chilcott would have had to defeat each of Lupin's arguments regarding invalidity and unenforceability and prove that Lupin infringed the '394 Patent. Warner Chilcott instead decided to protect its monopoly by paying Lupin to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24. And that is precisely what it did, in concert with Lupin.

**D. Warner Chilcott and Lupin Enter an Exclusion Payment Agreement**

93. Warner Chilcott made sure that the second ANDA-filer for Loestrin 24 Fe—Lupin—would not break any bottleneck caused by its Exclusion Payment Agreement with Watson by obtaining such a court decision. Before the court reached a determination on the issue of invalidity and/or non-infringement of the '394 Patent, Warner Chilcott paid Lupin too, pursuant to the Exclusion Payment Agreement, to drop its patent challenge and stay out of the market until after Watson was permitted to enter the market under Watson's unlawful agreement with Warner Chilcott.

94. On or about October 10, 2010, before the close of fact discovery and before the court could issue any substantive rulings, Warner Chilcott entered into a non-competition agreement with Lupin, whereby Warner Chilcott agreed to pay Lupin substantial sums in exchange for Lupin's agreement to delay marketing its less expensive generic version of



Loestrin 24 Fe until July 22, 2014, the month that the '394 Patent is set to expire. Pursuant to that Agreement, Warner Chilcott ended its '394 Patent litigation against Lupin, and Lupin dropped its Counterclaims against Warner Chilcott.

95. As the *quid pro quo* for Lupin's agreement to drop its challenge to the '394 Patent and to delay entry of its generic Loestrin 24, Warner Chilcott agreed to pay Lupin substantial sums. Warner Chilcott's payments to Lupin under the Agreement took at least two forms.

96. First, the agreement granted to Lupin a non-exclusive license covering Femcon Fe, another branded oral contraceptive manufactured by Warner Chilcott, which permitted Lupin to begin marketing an authorized generic version of Femcon Fe, supplied by Warner Chilcott, in the United States beginning on the earlier of (i) 180 days after the date that Teva Pharmaceutical Industries, Ltd (the "first-filer" with respect to Femcon Fe) entered the market with a generic equivalent to Femcon Fe, or (ii) January 1, 2013. Pursuant to the agreement, Lupin in fact entered the market with generic Femcon Fe, marketed as WYMZYA Fe, in October 2011, and since that time has made substantial sales of that product. But for this settlement, Lupin could not have begun making Femcon FE sales until the end of the 30 month stay in February 2012, assuming that Lupin would have entered at risk at that time.

97. Second, the agreement gave Lupin the right to purchase and sell in the United States a generic version of Asacol 400 mg (a branded treatment for inflammatory bowel disease), to be supplied by Warner Chilcott, if a generic version of the Asacol 400 mg product is launched by another generic manufacturer in the United States.

98. Warner Chilcott made these payments in exchange for Lupin's agreement to delay generic competition to Loestrin 24 for more than two years (unless another generic entered the market first, which Warner Chilcott prevented through additional agreements

described elsewhere in this complaint). Absent Lupin's agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not have agreed to: (a) grant to Lupin the nonexclusive license to make or sell generic Femcon Fe; (b) grant to Lupin the license to make or sell, under certain circumstances, a generic version of Asacol 400 mg; and/or (c) grant the price and/or other terms that it did under those provisions of the agreement. Warner Chilcott paid Lupin for delayed market entry of generic Loestrin 24.

99. As described more fully below, Warner Chilcott delayed generic entry in order to both protect its Loestrin 24 monopoly and buy time to permit it to switch of prescriptions to Warner Chilcott's follow-on branded version of Loestrin before generic Loestrin 24 became available.

#### **VI. THE ANTICOMPETITIVE SCHEME: SWITCH PRESCRIPTIONS FROM LOESTRIN 24 TO LO LOESTRIN**

100. In order to continue to exploit the market "disconnect" and maintain as many supracompetitive sales and profits as possible, it was necessary for Warner Chilcott to defeat the successful entry of generic Loestrin. In response to this anticipated competitive threat, Warner Chilcott devised a so-called "life cycle management" plan which involved (among other things) the rote filing of patent infringement cases regardless of their merit, unlawful pay-offs to generic manufacturers, and modifications to the Loestrin product — modifications that deliver no benefits to patients but that effectively shield substantial Loestrin sales from generic competition.

101. Using the time that it obtained by automatically filing patent litigation in order to obtain 30-month stays, and by paying off generic manufacturers to delay entry, Warner Chilcott modified the chemical composition of its Loestrin product so generic versions of Loestrin, when they finally did enter the market, would not be substitutable for branded Loestrin. Warner

Chilcott designed this "product hop" in order to protect as many Loestrin sales as possible from generic competition.

102. On March 26, 2009, Warner Chilcott submitted an application to the FDA for approval to market a revised version of Loestrin, which ultimately became known as Lo Loestrin Fe. Lo Loestrin offered no new benefits to consumers, as compared to the benefits of Loestrin 24. Both versions of the product contain the same active ingredients. In fact, the introduction of Lo Loestrin was actually disadvantageous to patients who had previously been taking Loestrin 24, due to the well-documented difficulties and dangers inherent in changing patients from one oral contraceptive to another. Most troubling, the clinical studies for Lo Loestrin revealed that the pregnancy rate (Pearl Index) for women using Lo Loestrin was 2.92 pregnancies per 100 women-years of use. This is more than 60% higher than the rate for Loestrin 24 Fe, which is 1.82.

103. If Lo Loestrin were superior, Warner Chilcott would have developed and marketed Lo Loestrin sooner than it did. Warner Chilcott's delay in developing and marketing Lo Loestrin until just before the onset of generic competition confirms that Warner Chilcott developed and marketed Lo Loestrin not because it was superior to Loestrin 24, but because it was part of an effective strategy to impair generic competition.

104. In fact, Warner Chilcott fully expected that, but for the effect of impairing generic competition, launching Lo Loestrin would cause Warner Chilcott to lose sales and revenues, increase its costs, and decrease its efficiency.

105. It was essential to Warner Chilcott that it launch and convert as many Loestrin 24 prescriptions as possible to Lo Loestrin before generic versions of Loestrin 24 were available in the market. Beating the generics onto the market would allow Warner Chilcott to effect the

switch at a time when no competing manufacturer had the incentive or ability to counter Warner Chilcott's marketing message to doctors.

106. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p.356 (<sup>8</sup> July 2009), available at [http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical sector inquiry fianl?start=006-00c=10](http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical%20sector%20inquiry%20final?start=006-00c=10). Industry analysts in the United States echo that conclusion, warning brand manufacturers that "it is essential that the brand holder switch their patients to the new formulation prior to generic launch." Stephen Perrett, *The Modified-Release Drug Delivery Landscape: The Commercial Perspective*, in II MODIFIED-RELEASE DRUG DELIVERY TECHNOLOGY 1, 3 (Michael J. Rathbone et al. eds., 2d ed. 2008).

107. Lo Loestrin offers no medical, convenience, or other benefits to consumers, as compared to Loestrin 24. Consequently, Warner Chilcott's ploy of switching prescriptions to Lo Loestrin depended on launching Lo Loestrin before generic versions of Loestrin 24 were available. Absent Warner Chilcott's unlawful payments to Watson and Lupin, generic Loestrin 24 would have been available long before the FDA approved Lo Loestrin for sale. Thus, Warner Chilcott would not have launched Lo Loestrin or, if it had, it would have made few sales.



108. Due to Warner Chilcott's anticompetitive scheme and unlawful payments to Watson and Lupin to delay entry, by the time generic Loestrin 24 is available in January 2014, the prescription base for Loestrin 24 will have been very substantially eroded.

## **VII. ANTICOMPETITIVE EFFECTS OF THE SCHEME**

109. Warner Chilcott's scheme and payments to suppress generic competition to Loestrin 24 have delayed and substantially diminished the sale of generic Loestrin 24. By delaying the onset of generic competition and reducing the prescription base, Defendants deprived would-be generic versions of the most efficient means of distribution under the governing statutory and regulatory regime.

110. Warner Chilcott's overarching anticompetitive scheme, and the Generic Defendants' participation in it, delayed and substantially diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated prices. But for Defendants' illegal conduct, generic manufacturers would have been able to enter the market unimpeded and compete on the merits against Loestrin 24. Generic competitors would also have been able to compete earlier, as early as September 2009, and additional generic competitors would have entered the market thereafter. Defendants' conduct unlawfully prevented purchasers of Loestrin 24 from obtaining the benefits of unimpaired generic competition.

111. Defendants' scheme and unlawful payments harmed Plaintiff and the End-Payor Class by depriving them of: (1) a market in which manufacturers and distributors of generic drugs make their decisions about challenging patents and entering markets free from the influence of unlawful payments; and (2) the most cost efficient means of distribution. Contrary to the purpose of the Hatch-Waxman Act, the anticompetitive scheme

and payments have enabled Defendants to: (a) delay the entry of less expensive generic versions of Loestrin 24 in the United States; (b) fix, raise, maintain or stabilize the price of Loestrin 24; (c) allocate 100% of the U.S. market for an oral contraceptive comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets to Warner Chilcott.

112. But for the anticompetitive scheme: (i) Watson would have begun selling AB-rated generic versions of Loestrin 24 on or shortly after receiving final FDA approval of its generic Loestrin 24 ANDA on September 1, 2009; and (ii) an increasingly competitive market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets would have emerged; and (iii) Warner Chilcott would not have developed or marketed Lo Loestrin and switched a substantial portion of sales to that product and/or generic Loestrin 24 would have entered the market before Lo Loestrin, and Warner Chilcott would have been able to switch no or few prescriptions to Lo Loestrin.

113. Defendants' unlawful conduct has delayed and diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Loestrin 24 would have occurred already, because, at a minimum, Watson would have already launched its generic version of Loestrin 24 and Warner Chilcott or its designee would have entered the market with an authorized generic version of Loestrin 24.

114. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

## VIII. CLASS ACTION ALLEGATIONS

115. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representative of an End-Payor Class defined as follows:

All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Loestrin 24 Fe in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "End-Payor Class"), other than for resale, during the period September 1, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" Loestrin 24 Fe if they paid or reimbursed for some of or the entire purchase price.

116. The following persons or entities are excluded from the proposed End-Payor Class:

- a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
- b. All governmental entities, except for governmental funded employee benefit plans;
- c. All persons or entities who purchased Loestrin 24 Fe for purposes of resale or directly from Defendants or their affiliates;
- d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);
- e. Any "flat co-pay" consumers whose purchases were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price;
- f. The judges in this case and any members of their immediate families.

117. Members of the End-Payor Class are so numerous that joinder is impracticable. Plaintiff believes that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

118. Plaintiff's claims are typical of those of the members of the End-Payor Class. Plaintiff and all members of the End-Payor Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for Loestrin 24 Fe and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Loestrin 24 Fe as a result of Defendants' wrongful conduct.

119. Plaintiff will fairly and adequately protect and represent the interests of the End-Payor Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the End-Payor Class.

120. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience in class action antitrust litigation involving pharmaceutical products.

121. Questions of law and fact common to the members of the End-Payor Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire End-Payor Class, thereby making overcharge damages with respect to the End-Payor Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

122. Questions of law and fact common to the End-Payor Class include, but are not limited to:

- a. Whether Defendants conspired to implement an overarching anti-competitive scheme to suppress generic competition to Loestrin 24;
- b. whether Defendants Warner Chilcott and Watson entered into an unlawful agreement in restraint of trade;
- c. whether, pursuant to the agreement, Watson agreed to delay its entry into the market with generic Loestrin 24 Fe;
- d. whether, pursuant to the agreement, Warner Chilcott compensated Watson;



- e. whether Warner Chilcott's compensation to Watson was for a purpose other than delayed entry of generic Loestrin 24 Fe;
- f. whether Warner Chilcott's compensation to Watson was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;
- g. whether the agreement is *per se* illegal, illegal under a "quick look" analysis, or illegal under the rule of reason;
- h. whether Defendants Warner Chilcott and Lupin entered into an unlawful agreement in restraint of trade;
- i. whether, pursuant to the agreement, Lupin agreed to delay its entry into the market with generic Loestrin 24 Fe;
- J. whether, pursuant to the agreement, Warner Chilcott compensated Lupin;
- k. whether Warner Chilcott's compensation to Lupin was for a purpose other than delayed entry of generic Loestrin 24 Fe;
- l. whether Warner Chilcott's compensation to Lupin was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;
- m. whether the agreement is *per se* illegal, illegal under a "quick look" analysis, or illegal under the rule of reason;
- n. whether Warner Chilcott filed the patent litigations against the generic manufacturers without regard to the litigations' merit, in order to obtain the benefit of the automatic 30-month stay;
- o. whether, absent the delay caused by Defendants' unlawful payments, Warner Chilcott would have launched and marketed Lo Loestrin;
- P. whether Warner Chilcott introduced, priced, and marketed Lo Loestrin in order to diminish the prescription base of Loestrin 24;
- q. whether Warner Chilcott possessed market power over Loestrin 24 Fe;
- r. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;
- s. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- t. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and
- u. the quantum of aggregate overcharge damages to the Class.

123. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

124. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

#### **IX. INTERSTATE AND INTRASTATE COMMERCE**

125. At all material times, Warner Chilcott manufactured, promoted, distributed, and sold substantial amounts of Loestrin 24 in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

126. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Loestrin 24.

127. In furtherance of their efforts to monopolize and restrain competition in the market for Loestrin 24 and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

128. Defendants' anticompetitive conduct has substantial intrastate effects in that, inter alia, retailers within each state are foreclosed from offering less expensive generic Loestrin 24 to

end-payors inside each respective state. The foreclosure of generic Loestrin 24 directly impacts and disrupts commerce for end-payors within each state.

#### **X. MARKET POWER AND MARKET DEFINITION**

129. At all relevant times, Warner Chilcott had market power with respect to oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets because it had the power to maintain the price of the drug it sold as Loestrin 24 at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

130. A small but significant, non-transitory price increase above the competitive level for Loestrin 24 by Warner Chilcott would not have caused a loss of sales sufficient to make the price increase unprofitable.

131. At competitive price levels, Loestrin 24 does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Loestrin 24.

132. Some formulations of oral contraceptives have higher failure rates in certain classes of women, and they differ widely in their safety and side-effect profiles. The differing efficacy, safety and side effect profiles of different oral contraceptives play a critical role in doctors' selection of the most appropriate oral contraceptive for a particular patient. The FDA does not consider these products bioequivalent, and there is variation in the dosage of the active ingredients.

133. Even though there may be a number of different oral contraceptive pills a physician could have started a patient on, or in theory could switch a patient to, once the physician and patient find an oral contraceptive pill that is well-tolerated, it is very unlikely that

the patient will switch to a different oral contraceptive based on variations of price of 10% or less. Doctors generally select an oral contraceptive for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price.

134. For clinical reasons, among others, physicians and patients prefer Loestrin 24 to other products designed to prevent pregnancy. Due to, among other reasons, its use and varying ability to prevent pregnancy while causing shorter, lighter periods, Loestrin 24 is significantly differentiated from all products other than AB-rated generic versions of Loestrin 24.

135. The existence of other products designed to prevent pregnancy has not significantly constrained Warner Chilcott's pricing of Loestrin 24. At all relevant times, Warner Chilcott's price for Loestrin 24 has been at least 60% above its marginal cost of production, and at least 40% above its marginal cost including marketing costs. Warner Chilcott has never lowered the price of Loestrin 24 in response to the pricing of other branded oral contraceptives (or the generic versions of those other branded oral contraceptives).

136. Warner Chilcott needed to control only Loestrin 24 and its AB-rated generic equivalents, and no other products, in order to maintain the price of Loestrin 24 profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 would render Warner Chilcott unable to profitably maintain supracompetitive prices for Loestrin 24.

137. Warner Chilcott knew that entry of a generic version of Loestrin 24 would be a uniquely significant market event. The entry of other branded oral contraceptives (or generic versions of those other brands) did not take substantial sales from Loestrin 24 or cause



Warner Chilcott to lower its price. But Warner Chilcott predicted that entry of generic Loestrin 24 would immediately cause branded Loestrin 24 to lose well more than half of its unit sales. Likewise, Watson estimated that its generic version of Loestrin 24 would take essentially all of its sales from branded Loestrin 24 and few if any sales from other branded oral contraceptives (or generic versions of those other brands). Lupin predicted the same with respect to its generic version of Loestrin 24.

138. Warner Chilcott, Watson, and Lupin predicted that the competitive impact of a generic version on branded Loestrin 24 would be substantial. Among other things, all three Defendants predicted that entry of generic Loestrin 24 would deliver hundreds of millions of dollars of savings to consumers.

139. At all relevant times, Warner Chilcott has sold Loestrin 24 at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

140. Warner Chilcott had, and exercised, the power to exclude and restrict competition to Loestrin 24.

141. Warner Chilcott, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

142. To the extent that Plaintiff is legally required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets (*i.e.*, Loestrin 24 and its AB-rated generic equivalents). During the relevant time, Warner Chilcott has been able to

profitably maintain the price of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets well above competitive levels.

143. The relevant geographic market is the United States and its territories.

144. At all relevant times, Warner Chilcott's market share in the relevant product market was and remains 100%, implying a substantial amount of market power.

## **XI. MARKET EFFECTS AND DAMAGES TO THE CLASS**

145. But for the anticompetitive conduct alleged above, Watson would have entered the market with its generic Loestrin 24 as early as September 1, 2009, the date its ANDA 78-267 received final FDA approval. Warner Chilcott would have launched an authorized generic version of Loestrin 24 at that same time. Lupin and other generic manufacturers would have entered the market with additional generic version of Loestrin 24 thereafter.

146. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Loestrin 24 from generic competition.

147. Watson and Lupin have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

148. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Loestrin 24, has caused Plaintiff and the Class to pay more than they would have paid for oral contraceptives comprising 24

norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets absent Defendants' illegal conduct.

149. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, end-payors rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

150. But for Defendants' anticompetitive conduct, end-payors, such as Plaintiff and members of the Class, would have paid less for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets by: (a) substituting purchases of less-expensive AB-rated generic Loestrin 24 for their purchases of more-expensive branded Loestrin; (b) receiving discounts on their remaining branded Loestrin 24 purchases; and (c) purchasing generic Loestrin 24 at lower prices sooner.

151. Moreover, due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Loestrin 24, and/or (b) challenging the validity or infringement of the '394 patent in court.

152. During the Class Period, Plaintiff and other members of the Class purchased substantial amounts of Loestrin 24. As a result of Defendants' illegal conduct as alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets. Plaintiff and the other Class members paid prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic Loestrin 24 instead of expensive brand Loestrin 24; and (2) Class members paid artificially inflated prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets.

153. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

154. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

## **XII. ANTITRUST IMPACT**

155. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of brand Loestrin 24 indirectly from or others. As a result of Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated prices for their oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets requirements. Those prices were substantially greater than the prices that members of the Class would have



paid absent the illegal conduct alleged herein, because: (1) the price of brand Loestrin 24 Fe was artificially inflated by Defendants' illegal conduct, (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Loestrin 24.

156. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

157. Overcharges at a higher level of distribution generally result in higher prices at every level below.

158. Wholesalers and retailers passed on the inflated prices of Loestrin 24 to the End-Payors defined herein.

159. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

160. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

161. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

### **XIII. CLAIMS FOR RELIEF**

#### **FIRST CLAIM FOR RELIEF**

#### **For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Violations of Section 1 of the Sherman Act (Asserted Against Warner Chilcott and Watson)**

162. Plaintiff repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

163. The Exclusion Payment Agreement between Warner Chilcott and Watson involves: (a) payments from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 Fe until January 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Watson under the Agreement were the *quid pro quo* for Watson's agreement to delay marketing its generic version of Loestrin 24 Fe for over four years. Absent the payments, Watson would not have agreed to delay marketing its generic version of Loestrin 24 Fe until January 22, 2014.

164. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Watson was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for up to over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets at the higher, branded price.

165. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

166. The Exclusion Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman

Act, 15 U.S.C. § 1. The Exclusion Payment Agreement is a horizontal market allocation and price fixing agreement between actual or potential competitors that is unlawful under the *per se*, "quick look" or rule of reason standard. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the Agreement was to delay generic competition to Loestrin 24 Fe and there is and was no legitimate, nonpretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

167. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

168. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic competition to Loestrin 24 Fe in each of the states and in the United States and enable Warner Chilcott to continue charging supracompetitive prices for Loestrin 24 Fe without a substantial loss of sales. By means of the Warner Chilcott's payments to Watson, the Defendants shared the supracompetitive profits that their unlawful agreement made possible.

169. Defendants each committed at least one overt act in furtherance of the conspiracy.

170. As a direct and proximate result of Defendants' unlawful restraint of trade Plaintiff and members of the Class were harmed as described herein.

171. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct as described herein violates Section 1 of the Sherman Act.

172. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

**SECOND CLAIM FOR RELIEF**  
**For Conspiracy and Combination in Restraint of**  
**Trade Under State Law**  
**(Asserted Against Warner Chilcott and Watson)**

173. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

174. The Exclusion Payment Agreement between Warner Chilcott and Watson involves: (a) a payments from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 Fe until January 22, 2014. The payments from Warner Chilcott to Watson under the Agreement were the *quid pro quo* for Watson's agreement to delay marketing its generic versions of Loestrin 24 Fe for as long as six years or more. Absent the payments, Watson would not have agreed to delay marketing its generic versions of Loestrin 24 Fe until January 22, 2014.

175. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the Exclusion Payment Agreement was to delay generic competition to Loestrin 24 Fe and there is and was no legitimate, nonpretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

176. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Watson was to allocate 100% of the market for Loestrin 24 and its generic equivalents in each of the states and in the United States to Warner Chilcott; delay



the sales of generic Loestrin 24 Fe products for up to over six years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

177. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

178. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiff and members of the Class paid artificially inflated prices for Loestrin 24 and were harmed as a result.

179. By engaging in the foregoing conduct, Defendants have violated the following state laws:

- a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Loestrin 24 Fe in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Loestrin 24 Fe in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Loestrin 24 Fe in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 Fe in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.
- e. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 815 ILCS § 50511, *et seq.* with respect to purchases of Loestrin 24 Fe in Illinois by members of the Class, and this conduct constitutes a predicate act under the Illinois Deceptive Trade Practices Act.

- f. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Kansas by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Maine by members of the Class.
- h. Defendant have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Loestrin 24 Fe in Massachusetts by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Loestrin 24 Fe in Michigan by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Loestrin 24 Fe in Minnesota by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in Mississippi by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nebraska by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nevada by members of the Class, in that thousands of sales of Loestrin 24 Fe took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- n. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in New Mexico by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York General Business Law

§ 340, *et seq.*, with respect to purchases of Loestrin 24 Fe in New York by members of the Class.

- p. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Carolina by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Dakota by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Loestrin 24 Fe in Oregon by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 258 with respect to purchases of Loestrin 24 Fe in Puerto Rico by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in South Dakota by members of the Class.
- u. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 Fe at Tennessee pharmacies.
- v. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 Fe in Utah by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Loestrin 24 Fe in Vermont by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in West Virginia by members of the Class.

- y. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Loestrin 24 Fe in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Loestrin 24 Fe at Wisconsin pharmacies.

180. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

181. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**THIRD CLAIM FOR RELIEF**  
**For Declaratory and Injunctive Relief Under**  
**Section 16 of the Clayton Act for Defendants'**  
**Violations of Section 1 of the Sherman Act**  
**(Asserted Against Warner Chilcott and Lupin)**

182. Plaintiff repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

183. The Exclusion Payment Agreement between Warner Chilcott and Lupin involves: (a) payments from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing its generic Loestrin 24 Fe until July 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Lupin under the Agreement were the *quid pro quo* for Lupin's agreement to delay marketing its generic version of Loestrin 24 Fe



for over four years. Absent the payments, Lupin would not have agreed to delay marketing its generic version of Loestrin 24 Fe until July 22, 2014.

184. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Lupin was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for up to over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets at the higher, branded price.

185. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

186. The Exclusion Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Exclusion Payment Agreement is a horizontal market allocation and price fixing agreement between actual or potential competitors that is unlawful under the *per se*, "quick look" or rule of reason standard. The purpose and effect of the payments flowing from Warner Chilcott to Lupin under the Agreement was to delay generic competition to Loestrin 24 Fe and there is and was no legitimate, nonpretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

187. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

188. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic competition to Loestrin 24 Fe and enable Warner Chilcott to continue charging supracompetitive prices for Loestrin 24 Fe without a substantial loss of sales. By means of the Warner Chilcott's payment to Lupin, the Defendants shared the supracompetitive profits that their unlawful agreement made possible.

189. Defendants each committed at least one overt act in furtherance of the conspiracy.

190. As a direct and proximate result of Defendants' unlawful restraint of trade Plaintiff and members of the Class were harmed as described herein.

191. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct as described herein violates Section 1 of the Sherman Act.

192. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

**FOURTH CLAIM FOR RELIEF**  
**For Conspiracy and Combination in Restraint of**  
**Trade Under State Law**  
**(Asserted Against Warner Chilcott and Lupin)**

193. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

194. The Exclusion Payment Agreement between Warner Chilcott and Lupin involves:  
(a) payments from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing

its generic Loestrin 24 Fe until July 22, 2014. The payments from Warner Chilcott to Lupin under the Agreement were the *quid pro quo* for Lupin's agreement to delay marketing its generic versions of Loestrin 24 Fe for as long as six years or more. Absent the payments, Lupin would not have agreed to delay marketing its generic versions of Loestrin 24 Fe until July 22, 2014.

195. The purpose and effect of the payments flowing from Warner Chilcott to Lupin under the Exclusion Payment Agreement was to delay generic competition to Loestrin 24 Fe and there is and was no legitimate, nonpretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

196. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Lupin was to allocate 100% of the market for Loestrin 24 and its generic equivalents in the United States to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for up to over six years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

197. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

198. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiff and members of the Class paid artificially inflated prices for Loestrin 24 as described herein, and were harmed as a result.

199. By engaging in the foregoing conduct, Defendants have violated the following state laws:

- a. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Loestrin 24 Fe in Arizona by members of the Class.

- b. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Loestrin 24 Fe in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Loestrin 24 Fe in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 Fe in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.
- e. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 815 ILCS § 50511, *et seq.* with respect to purchasers of Loestrin 24 Fe in Illinois by members of the Class and this conduct constitutes a predicate act under the Illinois Deceptive Trade Practices Act.
- f. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Loestrin 24 Fe and AB-rated generic equivalents in Kansas by members of the Class.
- g. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Maine by members of the Class.
- h. Defendant have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Loestrin 24 Fe in Massachusetts by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Loestrin 24 Fe in Michigan by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Loestrin 24 Fe in Minnesota by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et*



*seq.*, with respect to purchases of Loestrin 24 Fe in Mississippi by members of the Class.

- l. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nebraska by members of the Class.
- m. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nevada by members of the Class, in that thousands of sales of Loestrin 24 Fe took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- n. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in New Mexico by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Loestrin 24 Fe and AB-rated generic equivalents in New York by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Loestrin 24 Fe and AB-rated generic equivalents in North Carolina by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Dakota by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Loestrin 24 Fe in Oregon by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 10 L.P.R.A. § 258 with respect to purchases of Loestrin 24 Fe in Puerto Rico by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in South Dakota by members of the Class.



- u. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 Fe at Tennessee pharmacies.
- v. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 Fe in Utah by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Loestrin 24 Fe in Vermont by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in West Virginia by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Loestrin 24 Fe in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Loestrin 24 Fe at Wisconsin pharmacies.

200. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

201. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**FIFTH CLAIM FOR RELIEF**  
**For Unfair And Deceptive Trade Practices Under**  
**State Law**  
**(Asserted Against All Defendants)**

202. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

203. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and class members were deprived of the opportunity to purchase a generic version of Loestrin 24 Fe and forced to pay higher prices. By engaging in the foregoing conduct, Defendants have violated the following state Unfair and Deceptive Trade Practices and Consumer Fraud laws:

- a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*, with respect to purchases of Loestrin 24 Fe in Arizona by members of the Class.
- b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect to purchases of Loestrin 24 Fe in California by members of the Class.
- c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Loestrin 24 Fe in Florida by members of the Class.
- d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*, with respect to purchases of Loestrin 24 Fe in Illinois by members of the Class.
- e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*, with respect to purchases of Loestrin 24 Fe in Kansas by members of the Class.
- f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of Loestrin 24 Fe in Maine by members of the Class.

- g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Loestrin 24 Fe in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for Loestrin 24 Fe in actions and transactions occurring substantially within Massachusetts.
- h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, with respect to purchases of Loestrin 24 Fe in Michigan by members of the Class.
- i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Loestrin 24 Fe in Minnesota by members of the Class.
- j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nebraska by members of the Class.
- k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nevada by members of the Class.
- l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A: 1, *et seq.*, with respect to purchases of Loestrin 24 Fe in New Hampshire by members of the Class.
- m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in New Mexico by members of the Class.
- n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of Loestrin 24 Fe in New York by members of the Class.
- o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Carolina by members of the Class.
- p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in South Dakota by members of the Class.
- q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Tennessee by members of the Class.

- r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in Utah by members of the Class.
- s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451 *et seq.*, with respect to purchases of Loestrin 24 Fe in Vermont by members of the Class.
- t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in West Virginia by members of the Class.

204. Plaintiff and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair or deceptive acts alleged in this Claim. Their injury consists of paying higher prices for Loestrin 24 Fe than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

**SIXTH CLAIM FOR RELIEF**

**Unjust Enrichment (Forty-Eight States (all except Ohio and Indiana) & the District of Columbia, (Asserted Against All Defendants))**

205. Plaintiff hereby incorporates each preceding paragraph as though fully set forth herein.

206. Defendants have benefited from splitting the monopoly profits on Warner Chilcott's Loestrin 24 Fe sales resulting from the unlawful and inequitable acts alleged in this Complaint.

207. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Loestrin 24 by Plaintiff and members of the Class.

208. Plaintiff and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.



209. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiff and the Class.

210. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Loestrin 24 Fe or its generic equivalents, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

211. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for Loestrin 24 Fe and/or its generic equivalents is a direct and proximate result of Defendants' unlawful practices.

212. The financial benefits derived by Defendants rightfully belongs to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

213. It would be inequitable under the laws of all states and jurisdictions within the United States for the Defendants to be permitted to retain any of the overcharges for Loestrin 24 Fe derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

214. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds received by them.

215. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiff and the Class.

216. Plaintiff and the Class have no adequate remedy at law.



#### **XIV. DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiff, on behalf of itself and the End-Payor Class, demands judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiff representative of the End-Payor Class;

B. Declare that the conduct alleged herein is in violation of Section 1 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment under the laws of all states and jurisdictions within the United States;

C. Enjoin Defendants from continuing the illegal activities alleged herein;

D. Enter joint and several judgments against Defendants in favor of Plaintiff and the End-Payor Class;

E. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. Award the End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiff and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

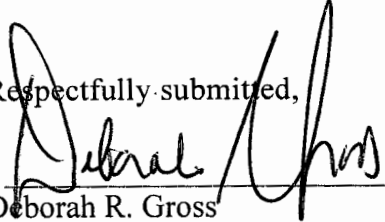
#### **XV. JURY DEMAND**

Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed Class demand a trial by jury on all issues so triable.

Dated: July 12, 2013

Respectfully submitted,

BY:

  
Deborah R. Gross

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